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No. 02-27

IN THE
Supreme Court of the United States

ALLINA HEALTH SYSTEM CORP., *et al.*,
Petitioners,

v.

UNITED STATES OF AMERICA, EX REL. MINNESOTA ASSOCIATION OF NURSE ANESTHETISTS,
Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eighth Circuit

MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE AND BRIEF AMICI CURIAE FOR THE AMERICAN HOSPITAL ASSOCIATION, THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, AND THE MINNESOTA HOSPITAL AND HEALTHCARE PARTNERSHIP IN SUPPORT OF PETITIONERS

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MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

Pursuant to Supreme Court Rule 37.2, the American Hospital Association (AHA), the Catholic Health Association of the United States (CHA), and the Minnesota Hospital and Healthcare Partnership (MHHP) move for leave to file the attached brief amici curiae in support of the petition. Petitioners have consented to the filing of this brief. Respondent has not consented, necessitating this motion.

AHA is the national advocacy organization for hospitals in this country. It represents approximately 5,000 hospitals, health systems, networks, and other care providers. AHA's mission is to promote high-quality health care and health

services through leadership and assistance to hospitals in meeting the health care needs of their communities.

The Catholic Health Association of the United States (CHA) is the national leadership organization representing the Catholic health ministry. CHA's more than 2,000 members form the nation's largest group of not-for-profit Catholic health care systems, sponsors, facilities, health plans, and related organizations. Catholic health care systems and facilities are present in all 50 states and are active in developing integrated networks and partnerships across the full continuum of health care.

The Minnesota Hospital and Healthcare Partnership (MHHP) is a non-profit, statewide advocacy organization representing all of Minnesota's 140 non-profit, community-based hospitals and 19 health systems. MHHP is committed to helping its members provide affordable access to quality health care for all Minnesotans. As an association, MHHP provides valuable compliance training programs for hospitals and health systems, seeks regulatory reforms, and strives to improve patient safety efforts, emergency preparedness planning and work force environments for hospitals to meet the needs of their communities.

Amici's members deliver health care services to millions of Americans. The federal government reimburses providers for many of those services in whole or in part through Medicare, Medicaid, CHAMPUS, and other federal health care programs.

One way in which amici promote the interests of their members is by participating as amicus curiae in cases where the outcome will have important and far-ranging consequences for their members. *See, e.g.*, *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000) (AHA amicus brief); *Vermont Agency of Natural Res.* v. *United States ex rel. Stevens*, 529 U.S. 765 (2000) (same); *Washington* v. *Glucksberg*, 521 U.S. 702 (1997) (CHA amicus brief).

This is such a case. As participants in the Medicare program, amici's members must comply with the program's complex regulatory standards governing reimbursement of provider claims. Their members are also subjected to qui tam lawsuits brought by private citizens under the False Claims Act, a powerful enforcement statute that, among other things, provides for penalties of up to $11,000 for *each* "false claim" submitted to the Government. The Eighth Circuit concluded that the hospital petitioners "were on notice of the possibility" that their interpretation of governing regulations was subject to question, reversed a District Court's grant of summary judgment for the petitioners, and remanded for a trial on the relator's claims. Following the Eighth Circuit's opinion, False Claims Act relators can survive summary judgment simply by pointing to another reasonable interpretation of the regulation in question. That standard conflicts with the standard articulated by several other courts of appeal.

Amici are uniquely situated to assess the practical implications of the Eighth Circuit's ruling and the need for resolution of the conflict the decision creates. In particular, amici will highlight for the Court the magnitude and complexity of the Medicare regulations forming the basis for this and other False Claims Act lawsuits, and the grave problems posed by the Eighth Circuit's overly lenient standard for sending False Claims Act suits to the jury.

Accordingly, AHA, CHA, and MHHP respectfully request that the Court grant this motion for leave to file the attached brief amici curiae.

Respectfully submitted,

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BRIEF FOR AMICI CURIAE AMERICAN HOSPITAL ASSOCIATION, THE CATHOLIC HEALTH ASSOCIATION OF THE UNITED STATES, AND THE MINNESOTA HOSPITAL AND HEALTHCARE PARTNERSHIP IN SUPPORT OF PETITIONERS

STATEMENT OF INTEREST OF AMICI CURIAE[1]

Founded in 1898, amicus American Hospital Association (AHA), is the national advocacy organization for hospitals in this country. It represents approximately 5,000 hospitals,

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[1] No counsel for any party authored this brief in whole or in part, and no person or entity, other than the amici curiae and their members, made a monetary contribution to the preparation or submission of this brief. S. Ct. Rule 37.6.

health systems, networks, and other care providers. AHA leads, represents, and serves health care provider organizations that are committed to health care improvement. Amicus Catholic Health Association of the United States (CHA), founded in 1915, is the national leadership organization representing the Catholic health ministry. CHA's more than 2,000 members, present in all 50 states, form the nation's largest group of not-for-profit Catholic health care systems, sponsors, facilities, health plans, and related organizations. Amicus Minnesota Hospital and Healthcare Partnership (MHHP) is a non-profit, statewide advocacy organization representing all of Minnesota's 140 non-profit, community-based hospitals and 19 health systems. MHHP is committed to helping its members provide affordable access to quality health care for all Minnesotans.

The questions presented in this petition have tremendous practical importance to amici's members, many of whom are subjected to litigation initiated by private citizens under the False Claims Act. AHA has a strong commitment to ensuring that hospitals have the information and tools they need to comply with the vast array of federal and state laws and regulations governing Medicare and Medicaid reimbursement issues. AHA and CHA regularly provide updates to their members on guidance issued by the Centers for Medicare & Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).[2] AHA also has instituted a formal process with CMS to obtain additional guidance on complex regulatory interpretation issues that regularly arise when attempting to translate guidance into compliance. CHA likewise regularly engages CMS to clarify reimbursement rules and regulations, and recently facilitated the submission by its members of extensive comments to the

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[2] HCFA was renamed the Centers for Medicare and Medicaid Services on July 1, 2001. *See* http://cms.hhs.gov/about/reorg.asp (last modified Mar. 6, 2002).

Department of Health and Human Services addressing issues relating to burdensome reimbursement regulations.

The Eighth Circuit's opinion subjects False Claims Act defendants to jury trials whenever it can be shown that those defendants were "on notice" of other interpretations of governing regulations—even if the defendants' interpretation was reasonable, and even if, as in this case, defendants sought guidance from the Government on the proper interpretation of complex or ambiguous regulations. The Eighth Circuit's decision conflicts with the decisions of several other courts of appeal. And if it remains in place, the decision will threaten amici's members with substantially increased exposure to frivolous False Claims Act lawsuits, diverting precious resources away from patient care.

STATEMENT OF THE CASE

"Medicare and Medicaid regulations are among the most complicated and confusing regulatory schemes in the United States." Timothy P. Blanchard, American Health Lawyers Ass'n, *Medicare and Medicaid False Claims: Legal Complexities and Developing Issues* 41 (1996). Medicare is a "massive" and "complex" regulatory program, "embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). Providers are governed by over 132,000 pages of laws, rules, and regulations—three times the size of the Internal Revenue Code and regulations. *See Mayo Chronicles Medicare Regs: It's 132,720 Pages of Red Tape*, Mod. Healthcare, Mar. 15, 1999, at 64 (describing page by page inventory of Medicare regulations); *Rx for the Health Care System,* Wall St. J., Oct 8, 1998, at A18.

This Court and the lower courts have often recognized that the Medicare statute and regulations are texts of practically inscrutable complexity—even by Congress's standards. *See, e.g., Schweiker* v. *Gray Panthers*, 453 U.S. 34, 43 (1981)

("The Social Security Act is among the most intricate ever drafted by Congress. Its Byzantine construction, as Judge Friendly has observed, makes the Act 'almost unintelligible to the uninitiated.' ") (quoting *Friedman* v. *Berger*, 547 F.2d 724, 727 n.7 (2d Cir. 1976), *cert. denied*, 430 U.S. 984 (1977)); *Rehabilitation Ass'n of Va., Inc.* v. *Kozlowski*, 42 F.3d 1444, 1450 (4th Cir. 1994) (Medicare statutes and regulations "are among the most completely impenetrable texts within human experience"), *cert. denied*, 516 U.S. 811 (1995).

Hospitals and health systems constantly must navigate this "morass of bureaucratic complexity," *Herweg* v. *Ray*, 455 U.S. 265, 279 (1982) (Burger, C.J., dissenting), submitting, on average, nearly 200,000 Medicare claims a day. *See Medicare Enforcement Actions: The Federal Government's Anti-Fraud Efforts: Hearing Before the Senate Special Comm. on Aging*, 107th Cong. 1 (2001) (testimony of AHA). To ensure compliance with the thicket of confusing—and sometimes conflicting—regulations comprising the Medicare reimbursement system, hospitals and other care providers regularly seek guidance from Government officials, as well as their "fiscal intermediaries"—private insurance companies under contract with the Government to process Medicare claims. *See* 42 U.S.C. § 1395h.[3] For practical reasons, however, providers cannot seek (and federal agencies and their agents are in no position to give) guidance on every last issue of regulatory interpretation that crops up when navigating Medicare's vast sea of regulations. In some circumstances, providers must simply examine and interpret the governing regulations as best they can.

When providers run afoul of Medicare's "impenetrable" regulations, *Rehabilitation Ass'n of Va.*, 42 F.3d at 1450,

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[3] A Medicare insurance carrier is "as a matter of law * * * an officer or employee of the United States." *Midland Psych. Assoc., Inc.* v. *United States*, 145 F.3d 1000, 1003 (8th Cir. 1998).

they expose themselves to potential liability under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. The Act provides for treble damages and penalties of $5,000-$10,000 for every "false claim" submitted to the Government. 31 U.S.C. § 3729(a).[4] The Act's qui tam provisions, under which private citizens may sue defendants on the Government's behalf, augment its powerful arsenal of remedies. *See* 31 U.S.C. § 3730(b). Over the past decade, False Claims Act lawsuits have proliferated. *See* W. Jay DeVecchio, *Qui Tam Actions: Some Practical Considerations*, ALI/ABA Course of Study, Health Care Law & Litigation 401 (Oct. 2001) (noting that 56 percent of qui tam cases filed since 1986 were brought in 1997 through 2000). And the fastest-growing subset of False Claims Act suits are those in the health care area.[5] The reason for the recent spate of False Claims Act suits against health care providers, some commentators argue, is "that health-care regulations have just become too complicated to understand." Uwe E. Reinhardt, *Medicare Can Turn Anyone into a Crook*, Wall St. J., Jan. 21, 2000, at A18; *see also* Joan H. Krause, *Health Care Providers And The Public Fisc: Paradigms Of Government Harm Under The Civil False Claims Act*, 36 Ga. L. Rev. 121, 146 (2001).

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[4] Department of Justice regulations increased penalties to $5,500-$11,000 for each false claim submitted on or after September 29, 1999. *See* 64 Fed. Reg. 47,099, 47,104 (Aug. 30, 1999).

[5] *See* Health, Educ. & Human Servs. Div., U.S. Gen. Accounting Office, *Medicare: Application of the False Claims Act to Hospital Billing Practices* 3 (July 1998) (noting that health care-related False Claims Act matters pending at the Department of Justice jumped from 270 matters in 1992 to over 4,000 in 1997); Dep't of Health & Human Servs. and Dep't of Justice, *Health Care Fraud and Abuse Control Program, Annual Report For FY 2001* (April 2002) (noting that "[a]t the end of 2001, [United States Attorney's Offices] had 1,746 civil health care fraud matters pending"), *available at* http://www.usdoj.gov/dag/pubdoc/hipaa01fe19.htm.

One of the Government's first False Claims Act enforcement initiatives against health care providers precipitated an important change in enforcement policy after it was criticized for labeling as "fraudulent" reasonable interpretations of ambiguous Government directives. In 1997, the Government began investigating hospitals' practice of "unbundling" laboratory tests—submitting separate bills for each procedure performed in a group of laboratory outpatient tests. During the investigation—dubbed with the military-style handle "Operation Bad Bundle"—hospitals received demand letters from United States Attorneys accusing them of having fraudulently claimed entitlement to payment for unbundled laboratory tests, demanding huge sums in repayment and penalties, and threatening law enforcement proceedings if settlement was not swiftly reached. But as an AHA report later demonstrated, the legal basis for the investigations was flawed. *See* Jones, Day, Reavis, & Pogue, Special Report to the American Hospital Association, *Development of Government Guidelines for Hospital Outpatient Laboratory Reimbursement* 45-57 (Mar. 1998). The "fraud" of which hospitals were being accused was the hospitals' allegedly failing to follow billing requirements that were never established through rulemaking, never issued as guidance by the agency, and that were actually *contradicted* in billing instructions from fiscal intermediaries. *See id.* at 55.

After the AHA and others sharply criticized "Operation Bad Bundle,"[6] then-Deputy Attorney General Eric Holder

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[6] After serious questions were raised about the Government's overreaching, the Government significantly curtailed "Operation Bad Bundle," withdrew its investigations in several states (and in one state actually refunded fines collected from hospitals), and terminated compliance agreements that were imposed as part of settlements. *See* Health, Educ. & Human Servs. Div., U.S. Gen. Accounting Office, *Medicare Fraud and Abuse: DOJ's Implementation of False Claims Act Guidance in National Initiatives Varies* 22-23 & n.11 (Aug. 1999); *Fraud and Abuse: Federal Prosecutors in Texas Back Off Operation Bad Bundle Due*

issued a memorandum specifically stating that whether a health care provider sought guidance on interpreting regulations is a critical threshold inquiry under the False Claims Act. Memorandum from Eric H. Holder, Jr., Deputy Attorney General (June 3, 1998), *reprinted at* Pet. App. 342. United States Attorneys evaluating whether a provider knowingly submitted false claims to the Government were directed, among other things, to consider whether the provider sought guidance from the "program agency or its agents":

> Did the provider directly contact either the program agency (*e.g.*, the Health Care Financing Administration [HCFA]) or its agents regarding the billing rule at issue? If so, was the provider forthcoming and accurate and did the provider disclose all material facts regarding the billing issue for which the provider sought guidance? Did the program agency or its agents, with disclosure of all relevant, material facts, provide clear guidance? Did the provider reasonably rely on such guidance in submitting the false claims? [Pet. App. 346 (Holder Memorandum at 3, para. (1)(A)(ii)(f)).]

Confronted with a knotty question of regulatory interpretation, the petitioner hospitals in this case sought guidance from one of their Medicare carriers, Travelers Insurance, on the question whether an anesthesiologist must remain at a patient's side during a procedure where a nurse-anesthetist was also present in order to certify that the anesthesiologist was "continuously involved" with that procedure. *See* Pet.

Prosecutors in Texas Back Off Operation Bad Bundle Due to Data Problems, Health Care Daily Rep. (BNA), Nov. 23, 1998, at D3. *See also* Krause, *supra*, at 146 (noting that "[o]n occasion, the government has had to retreat from high profile enforcement initiatives because of ambiguity in the reimbursement rules").

28; Pet. App. 393-400, 406.[7] Travelers instructed the hospitals that as long as anesthesiologists remained in the "operating suite"—which unrebutted evidence below established meant the hospital's complex of operating rooms and support facilities—anesthesiologists could represent that they had been "continuously involved" with a procedure. *See* 8th Cir. Appellees' App. 206 (noting that the anesthesiologist's "obligation is continuous *involvement* with the procedure, rather than, continuous *presence*") (emphasis added); *id.* at 385-387. At the petitioner hospitals' request, Travelers also sought clarification from HCFA on the same question. *Id.* at 388-389. HCFA confirmed Travelers' interpretation. *See id.* at 195-196.

The petitioner hospitals similarly sought guidance on the proper classification of nurse-anesthetist services performed in "medical necessity" cases—complicated surgeries that require two anesthesia providers. Under the controlling federal regulations, providers had two options: they could bill nurse-anesthetist services as "medically directed" or "non-medically directed." *See* 57 Fed. Reg. 33,878, 33,898-99 (July 31, 1992) (publishing 42 C.F.R. § 414.451(a)(1)-(2)). The petitioner hospitals' Medicare carriers instructed the hospitals to bill nurse anesthetist services performed in medical necessity cases as "medically directed." *See* 8th Cir. Appellees' App. 217 (Blue Cross provider manual), 381-384 (testimony of Travelers officer); *see also* 57 Fed. Reg. at 33,888 (response of HCFA to comments on proposed regulations) ("As a practical matter, as long as anesthesiologists are involved with CRNAs in anesthesia services, the CRNA would consider the procedure to be medically directed or medically supervised.").

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[7] Witnesses below testified that Medicare anesthesia regulations are the most complex of Medicare's medical specialty regulations. *See* 8th Cir. Appellees' App. 399-400, 579-580.

Respondent Minnesota Association of Nurse Anesthetists (MANA) filed a qui tam suit against the hospitals for, among other things, allegedly misrepresenting that anesthesiologists were "continuously involved" with anesthesia procedures when they were not continuously present during those procedures, and allegedly mis-billing nurse anesthetist services as "medically directed" when they were "non-medically-directed." The United States declined to intervene.

Dismissing MANA's suit, the District Court concluded that the False Claims Act's scienter requirement could not be satisfied.[8] Pet. App. 78-79. The court explained that MANA could not prove that the qui tam defendants "*knowingly* submitted false claims" when the controlling regulations were ambiguous and subject to a "range of reasonable interpretations," and when substantial record evidence demonstrated that defendants submitted their bills in accordance with Government guidance. *Id.* at 77-79.

The Eighth Circuit reversed. The court of appeals acknowledged that the False Claims Act requires relators to prove that defendants "knowingly" submitted false claims to the Government. *Id.* at 39. And the court correctly observed that the "standard for liability is knowing, not negligent, presentation of a false claim." *Id.* at 40. But the court then strayed widely from the course, stating that "while there may have been some uncertainty about the interpretation of 'continuously involved,' " the qui tam defendants "*were on*

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[8] The District Court also held that it lacked jurisdiction to hear MANA's claims because its allegations were publicly disclosed prior to the filing of the qui tam suit, and MANA—a nonprofit corporation—was not an "original source" of the disclosure. Pet. App. 65-73. And the District Court also concluded that the United States had not suffered injury as a result of the qui tam defendants' alleged fraudulent representations. *Id.* at 73-77. The Eighth Circuit reversed each of those holdings.

notice of the possibility" that their interpretation of the governing regulations was not correct. *Id.* (emphasis added). This bare "possibility," in the Eighth Circuit's view, gave rise to a "question of fact as to [petitioners'] state of mind," and required remand to the District Court for trial. *Id.*

That is quite plainly not the standard to which petitioners should have been held. The Eighth Circuit's formulation brings the court into sharp conflict with the holdings of several other courts of appeal, all of which have made clear that a qui tam defendant cannot be found *knowingly* to have submitted false claims when it was following—with Government guidance, no less—a reasonable interpretation of ambiguous controlling regulations.

SUMMARY OF ARGUMENT

Hospitals and other care providers strive daily to comply with Medicare's intricate web of reimbursement regulations. They seek guidance from federal agencies and their fiscal intermediaries, and they employ their best judgment to render reasonable interpretations of the regulations' complicated and often conflicting directives. Occasionally their interpretations turn out to be wrong. That does not make them "knowingly false." But by holding that the petitioners "were on notice of the possibility" of a different interpretation of the controlling regulations, the Eighth Circuit has allowed False Claims Act relators to bring their claims to a jury even where the relators lack *any* evidence that the claims were "knowingly false."

The Eighth Circuit's decision conflicts with the holdings of several other courts of appeal. Those courts have consistently held that False Claims Act defendants who seek out and reasonably rely on government guidance, or who demonstrate that they reasonably interpreted their governing regulations, are entitled to summary judgment, on grounds that the Act's scienter requirement cannot be met in those circumstances. The Eighth Circuit's decision substantially lowers

the bar for sending False Claims Act cases to the jury, and it does a grave disservice to hospitals and care providers making every reasonable attempt to comply with the morass of Medicare regulations to which they are subject.

ARGUMENT

QUI TAM DEFENDANTS WHO REASONABLY RELY ON GOVERNMENT GUIDANCE ARE ENTITLED TO SUMMARY JUDGMENT.

1. The False Claims Act ("Act") prohibits any person from "knowingly" presenting a "false or fraudulent" claim to the government. 31 U.S.C. § 3729(a). The Act defines "knowing" as actual knowledge of the falsity of the information, or deliberate ignorance or reckless disregard of the truth or falsity of the information presented to the government. 31 U.S.C. § 3729(b).

The Act's scienter requirement, as one court has observed, is "critical" to its operation. *United States ex rel. Hochman* v. *Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998). Innocent or negligent mistakes do not give rise to False Claims Act liability. *See United States ex rel. Oliver* v. *Parsons Co.*, 195 F.3d 457, 464-465 (9th Cir. 1999), *cert. denied*, 530 U.S. 1228 (2000). Rather, the Act requires that the defendant made a "*knowing* presentation of what is *known* to be false." *Hagood* v. *Sonoma County Water Agency*, 81 F.3d 1465, 1478 (9th Cir.) (quotation omitted and emphases added), *cert. denied,* 519 U.S. 865 (1996). "In short, the claim must be a lie." *Hindo* v. *University of Health Sciences/The Chicago Med. Sch.*, 65 F.3d 608, 613 (7th Cir. 1995), *cert. denied*, 516 U.S. 1114 (1996). Thus, as the Ninth Circuit has explained, "[a] contractor relying on a good faith interpretation of a regulation is not subject to liability, not because his or her interpretation was correct or 'reasonable' but because the good faith nature of his or her action forecloses the possibility that the scienter requirement is met." *Oliver*, 195 F.3d at 464. *See also United States ex rel. Mikes* v. *Straus*,

274 F.3d 687, 703 (2d Cir. 2001); *Wang* v. *FMC Corp.*, 975 F.2d 1412, 1420 (9th Cir. 1992).

As the Eighth Circuit framed the issue, the inquiry into the defendants' intent turned on whether defendants were "on notice of the possibility" that the controlling regulations might be interpreted in a manner inconsistent with their billing practices. Pet. App. 39-40. But it is not enough under the FCA for the defendant to be "on notice" of the possibility that the regulations may be interpreted to prohibit its conduct. The proper inquiry in this situation, rather, is whether the defendants reasonably relied on the guidance provided by the Government and its agents regarding billing for anesthesia services. As other courts have recognized, when a provider seeks guidance from the Government or its agent about an ambiguous regulation and acts in accordance with that guidance, the provider should be entitled to a presumption that claims submitted subject to that guidance were not knowingly false such that, absent specific rebuttal evidence, the provider is entitled to summary judgment.

This standard is not a free pass for False Claims Act defendants to automatically avoid liability at the summary judgment stage by concocting a post-hoc interpretation of an ambiguous regulation that is consistent with their conduct.[9] Rather, it properly allocates the burden of proof between the

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[9] The United States filed an amicus brief in the Eighth Circuit warning that an overly broad reading of the District Court's opinion might improperly "absolve of liability any defendant who can advance, post-hoc, a plausible regulatory basis for his submission of admittedly false claims." Brief of Amici Curiae United States at 26, *United States ex rel. Minnesota Ass'n of Nurse Anesthetists* v. *Allina Health Sys. Corp.*, 276 F.3d 1032 (8th Cir. 2002). That concern is not present in this case, where, as the District Court recognized, the defendants submitted "substantial evidence" that their interpretation of the regulations was not only reasonable, but was formed contemporaneously with their claim submissions and with Government guidance. *See* Pet. App. 78.

relator and the defendant in circumstances where the defendant has taken reasonable steps prior to submitting its claims to ensure their propriety.

2. Courts have repeatedly endorsed the principle that individuals should be allowed to act on legal guidance from the Government without fear of retribution, both in the context of the False Claims Act and well beyond.[10] *See United States* v. *Levin*, 973 F.2d 463 (6th Cir. 1992). The defendant physicians in *Levin*, charged with violations of the False Claims Act's criminal analog,[11] had participated in a marketing arrangement with suppliers of lens implants where the physicians received disposable surgical supplies with each purchase of a lens implant. *Id.* at 464. Before they implemented the arrangement, the suppliers had sought guidance from HCFA and had received assurances that the arrangement was legal. *Id.* at 465. Although the defendants themselves had not sought guidance on the issue, the HCFA opinion letters were circulated throughout their professional community. *Id.* When the physicians were later charged with making false claims, the district court dismissed the charges prior to trial. The Sixth Circuit affirmed, concluding that "the defendants and those similarly situated could not, as a matter of law, have formulated the necessary intent" to violate the Medicare fraud statute. *Id.* at 466.

The principle on which *Levin* turned—that individuals may defend against allegations of making false claims by pointing

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[10] The principle has its roots in due process concerns in the criminal context. *See United States* v. *Laub*, 385 U.S. 475, 487 (1967) ("Ordinarily, citizens may not be punished for actions undertaken in good faith reliance upon authoritative assurance that punishment will not attach.").

[11] The *Levin* defendants were charged with violations of 42 U.S.C. § 1395nn(b)(1)(B) (Medicare fraud); 18 U.S.C. § 287 (false claims); 18 U.S.C. § 1001 (false statements); and 18 U.S.C. § 1341 (mail fraud). 973 F.2d at 464.

to their reliance on Government guidance—has been repeatedly applied in civil False Claims Act cases. In *Hindo* v. *Univ. of Health Sciences/The Chicago Medical School*, 65 F.3d at 614, for example, a university billed a Veteran's Administration (VA) medical center for two radiology residents for whom the VA had not approved funding. In a subsequent False Claims Act qui tam suit, the Seventh Circuit upheld a directed verdict in the university's favor, noting that the university had been led to believe by the VA that the required funding would eventually be approved. *Id.* The Seventh Circuit concluded that "[n]o legitimate reading of the record can support an inference that [the university] *knew* that the possibility of funding was foreclosed" and nonetheless submitted false claims for reimbursement. *Id.* at 613-614 (emphasis added). Where the Government had given the university assurances that the positions would be funded, even if those assurances ultimately did not bear fruit, "[i]t was not unreasonable and certainly not fraudulent" for the university to submit claims for reimbursement for the unfunded residents. *Id.* at 614. At most, the court noted, the university was "perhaps negligent in not ascertaining whether funding had been approved * * *. But negligence is not actionable." *Id.*

Similarly, in *Hagood* v. *Sonoma County Water Agency*, 81 F.3d at 1478, the Ninth Circuit upheld summary judgment for the defendant in a False Claims Act case where the defendant had relied upon the Government's interpretation of the relevant regulation. At issue there was an agreement between a county and the Army Corps of Engineers for the county to reimburse the Corps for the water supply component of the cost of building a dam. *Id.* at 1467. The county based its reimbursement payment on an outdated cost allocation that was admittedly imprecise, if not flat wrong. *Id.* at 1477. The Corps told the county, however, that no new cost allocation would be performed. *Id.* at 1478.

Noting that the county "did merely what the Corps bid it do," the Ninth Circuit affirmed judgment for the defendant. *Id.* (quotation omitted). Whether the Corps was required to

perform a new, updated cost allocation better reflecting current data was, according to the evidence, a "disputed question within the Corps." *Id.* at 1477. By acting in reliance on the Corps' statement that it would not perform a new cost allocation, the defendant may have "take[n] advantage of a disputed legal question," but that was fair game under the Act; making the most of an uncertain legal issue did not render the defendant's actions so "deliberately ignorant nor recklessly disregardful" as to satisfy the Act's scienter requirement. *Id.* at 1478 (quotation omitted). *See also United States ex rel. Lamers* v. *City of Green Bay*, 998 F. Supp. 971, 991 (E.D. Wis. 1998) ("Exploring the boundaries of a disputed legal question is not actionable under the FCA"), *aff'd*, 168 F.3d 1013 (7th Cir. 1999).

Finally, in a case bearing many similarities to this one, *United States ex rel. Swafford* v. *Borgess Medical Center*, 98 F. Supp. 2d 822 (W.D. Mich. 2000), *aff'd*, 2001 WL 1609913 (6th Cir. 2001), *cert. denied*, 122 S. Ct. 2292 (2002), the defendant physicians were accused by a qui tam relator of submitting false claims for reimbursement for their evaluation of vascular ultrasounds. Under the controlling Medicare regulations, different billing rates applied depending on whether the ultrasound was performed and evaluated by a technician or a physician. *Id.* at 825. Technicians performed the actual tests, reviewed the data, and created a summary. Physicians based their reports on the technicians' worksheets. *Id.* The relator claimed that the physicians falsely billed for more expensive "professional" services, rather than "technical" interpretations, when they merely copied their conclusions from the technicians' summaries. *Id.* at 826.

The district court granted summary judgment for the defendants. First of all, the court noted, the question whether interpreting a technician's summary amounted to "professional" services was really a "dispute over the meaning of the terms governing the delivery of the professional component of physician services." *Id.* at 831-832. Such a "legal dispute" was insufficient to establish the *falsity* of a claim under

the False Claims Act. *Id.* at 832 (citing *Hagood*, 81 F.3d at 1477). Nor, the district court went on, could the relator prove scienter: the evidence showed that one defendant had sought guidance from HCFA about the proper billing modifier to use in such circumstances, and HCFA had responded that there were no specific guidelines published on the question. *Id.* at 832-833. The court observed that defendants' attempts to secure guidance from HCFA "suggests defendants evinced concern and investigated the question of what procedures were required to submit a proper claim for reimbursement." *Id.* at 833. Finding no other affirmative evidence—other than the relator's own bald speculation—suggesting that the defendants' practice recklessly disregarded applicable billing regulations, the court granted judgment for defendants. *Id.*

In each of these cases, as here, the evidence demonstrated that there existed a legal ambiguity in the governing regulations. In each case, the defendants were aware of the uncertainty in the law—that is, they were "on notice of the possibility" of a different interpretation of the regulations at the time they submitted their claims. In each case, the defendants either specifically sought guidance from the Government or relied upon representations made to others by the Government when submitting their claims. And in each case, the courts shielded the defendants from a False Claims Act trial by granting summary judgment in their favor. Consistent with the standard offered herein, and contrary to the approach taken by the Eighth Circuit, the courts recognized that unrebutted evidence of seeking and reasonably relying upon Government guidance created a strong presumption that any claims submitted pursuant to that guidance were not knowingly false.[12]

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[12] Indeed, even in denying or overturning judgment for a False Claims Act defendant on the scienter element, courts have emphasized the importance of seeking clarification from the Government of ambiguous regulations, noting that the outcome may have favored the defendants if they had affirmatively sought such clarification. *See, e.g., United States* v. *Cooperative Grain & Supply Co.*, 476 F.2d 47, 60 (8th Cir. 1973) (holding that the

3. MANA suggested to the courts below that the petitioners' interpretation of the regulations, even if reasonable, would not absolve them from False Claims Act liability. To begin with, it would be highly impracticable, if not impossible, for regulated entities to seek clarification from the Government on every ambiguity in their governing regulations. Courts have recognized as much, holding that even where False Claims Act defendants have *not* affirmatively sought specific guidance from the Government on the proper interpretation of a controlling regulation, evidence of a defendant's contemporaneous reasonable or good-faith belief that its interpretation was reasonable negates the False Claims Act's scienter element.

In *United States ex rel. Hochman* v. *Nackman*, 145 F.3d at 1075-76, for example, the Ninth Circuit held that where the defendants believed their conduct was authorized under a contract with the Government, the defendants were entitled to summary judgment. The relators in *Hochman* claimed, among other things, that the defendant hospital administrators and physicians had billed a VA clinic for times when the physicians were not physically present at the clinic. *Id.* at 1070.[13] The Affiliation Agreement under which the physicians provided their services did not address whether physicians would be paid for time they spent teaching or performing research outside the VA facility; the defendants had interpreted the Agreement to allow for such activities to be compensated. *Id.* at 1075.

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extreme carelessness with which the defendants submitted their claims satisfied the Act's scienter requirement, and noting that the case would "have been much different if the defendants at least had" sought clarification of the governing regulations).

[13] The relators in *Hochman* claimed that the defendants had violated the False Claims Act in three other respects as well. The Ninth Circuit concluded as to each of those three charges that the Act's scienter requirement was not satisfied. *See id.* at 1073-75.

Without deciding whether the defendants' interpretation of the Affiliation Agreement was wrong or right, the Ninth Circuit upheld summary judgment in favor of the defendants. The court of appeals noted that "the undisputed evidence demonstrates that the defendants believed that the Affiliation Agreement authorized their conduct." *Id.* The court further concluded that regardless of whether defendants' interpretation ultimately was incorrect, it was "at least superficially plausible" and was not "in reckless disregard of or deliberate indifference to" the controlling language. *Id.* "Without sufficient evidence to support an inference that the defendants understood that they were interpreting the Affiliation Agreement incorrectly," the court concluded, "the plaintiffs' claim must fail." *Id.* at 1076. *See United States ex rel. Mikes* v. *Straus*, 274 F.3d at 704 (upholding summary judgment for defendants where defendants proffered "ample evidence—most of which derives from disinterested non-party witnesses—supporting their contention that they held a good faith belief" that their Medicare reimbursement requests were legitimate); *United States ex rel. Norbeck* v. *Basin Elec. Power Coop.*, 248 F.3d 781, 793-794 (8th Cir. 2001) (reversing judgment against defendant; while rules governing defendant's practices were not clear, plaintiffs introduced no evidence from which an inference could be drawn that defendant *knew* it was overcharging the Government), *cert. denied*, 122 S. Ct. 924 (2002); *Lamers*, 998 F. Supp. at 991 (granting summary judgment for defendants where evidence showed that defendants were genuinely confused about the regulatory requirements at the time they submitted the allegedly false claims, and no evidence supported relator's claim that defendants had feigned ignorance in an elaborate scheme to defraud the government).

4. The relator below—and the United States as amicus curiae, *see supra* n.9—relied heavily on the Ninth Circuit's opinion in *United States ex rel. Oliver* v. *Parsons Co.*, 195 F.3d at 463, to support their contention that the defendants'

reasonable interpretation of the anesthesia regulations did not excuse them from liability. Far from supporting the relator's position here, *Oliver* in fact confirms that where defendants produce credible unrebutted evidence of their good-faith interpretation of a governing regulation—as the hospital defendants did in this case—they are entitled to summary judgment.

Oliver held that the *falsity* element of the False Claims Act cannot be satisfied merely by showing that the defendant employed a "reasonable interpretation" of the controlling regulations. *See* 195 F.3d at 460. That makes sense. A court reviewing a False Claims Act charge must interpret the governing regulations and determine whether a claim was false, and a "reasonable interpretation" standard would improperly trump that inquiry.

The primary question in this case, however, was not whether the defendant hospitals' interpretation of the anesthesia reimbursement rules negated the Act's falsity element, but whether the Act's *scienter* requirement was defeated when the defendant hospitals produced unrebutted evidence that they sought and reasonably relied on Government guidance in interpreting those regulations. *See* Pet. App. 77-78 (District Court decision addressing defendants' "intent to submit false claims"); *id.* 39 (Eighth Circuit opinion addressing intent element). The Ninth Circuit's "reasonable interpretation" discussion does not impact that question in the least, and its treatment of the scienter element squares with that of other circuits (except, of course, the Eighth). The *Oliver* panel concluded that a trial was required on the scienter element Act because the relator had produced compelling evidence of knowledge sufficient to preclude summary judgment.[14] Unlike the relator in *Oliver*, MANA in

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[14] The relator, an accountant at the defendant company, submitted an affidavit stating that when she brought the omission giving rise to the False Claims Act action to defendant's corporate

this case submitted *no* evidence that the defendant hospitals actually *knew* their interpretations of the governing regulations were wrong and that their Medicare reimbursement requests were false. Rather, as in *Hochman*, *Mikes*, and *Norbeck*, the hospitals offered substantial credible evidence that they reasonably interpreted the anesthesia regulations before they submitted their reimbursement claims.

CONCLUSION

For the foregoing reasons, as well as those presented in the petition, the petition should be granted and the Eighth Circuit's decision reversed.

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officers, she was told to "forget about it," and was further told that the omission was purposeful to allow the defendant to charge the government a higher rate for its services. 195 F.3d at 465.